

PATENT COOPERATION TREATY

REC'D 22 MAR 2005

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From the:
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Fisher Adams Kelly
GPO Box 1413
BRISBANE QLD 4001

Date of mailing (day/month/year)	16 MAR 2005
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Applicant's or agent's file reference
12846PC2

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/AU2005/000106

International filing date (day/month/year)
28 January 2005

Priority date (day/month/year)
28 January 2004

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. ⁷ A61M 5/315

Applicant
UNITRACT SYRINGE PTY LTD et al

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION


If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2005/000106

Box No. I	Basis of the opinion
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- | | |
|----|---|
| 1. | With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

<input type="checkbox"/> This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)). |
| 2. | With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

<input type="checkbox"/> a sequence listing
<input type="checkbox"/> table(s) related to the sequence listing

b. format of material

<input type="checkbox"/> in written format
<input type="checkbox"/> in computer readable form

c. time of filing/furnishing

<input type="checkbox"/> contained in the international application as filed.
<input type="checkbox"/> filed together with the international application in computer readable form.
<input type="checkbox"/> furnished subsequently to this Authority for the purposes of search. |
| 3. | <input type="checkbox"/> In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished. |
| 4. | Additional comments: |

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2005/000106

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims 5-10, 17-20, 22	YES
	Claims 1-4, 11-16, 21	NO
Inventive step (IS)	Claims 5-10, 17-20, 22	YES
	Claims 1-4, 11-16, 21	NO
Industrial applicability (IA)	Claims 1-22	YES
	Claims	NO

2. Citations and explanations:

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 US 4642102 (OHMORI)
- D2 GB 2203047 (BANKS et al)
- D3 WO 1989012476 (FAVARD)
- D4 ES 2031756 (GUTIERREZ DE CEPEDA)
- D5 WO 1994013339 (MALLINCKRODT MEDICAL, INC.)
- D6 US 5328476 (BIDWELL)
- D7 US 20010049506 (SCHOENFELD et al)

The present application defines a plunger for a syringe, the plunger having one or more longitudinal ratchet mechanisms and the syringe having one or more pawls that engage with the ratchet and prevent withdrawal of the plunger "during or following depression" (claims 1, 11 and 21)). This concept is further defined by the pawls being on the outer member of a collar mechanism mounted in the barrel of the syringe (claims 5 and 20). The collar also has an inner member that prevents the pawls from engaging the ratchet until the plunger is depressed.

Document D1 recites a syringe having a plunger (2) with a stopper mechanism (3) that abuts against the barrel of the syringe and prevents the plunger from being advanced beyond a certain length. The object is to produce a more accurate injection compared to a graduated syringe. Claims 1 to 22 are novel and inventive in view of this document.

D2 provides a syringe having a plunger with splines to prevent rotation of the plunger and ratchet teeth (28) engage with pawl (29) on the separate end plate (5). Teeth (28) and pawl (29) cooperate to prevent the plunger from being withdrawn once the injection stroke is commenced. In addition ratchet teeth (15) and pawl (16) on an opposite side of the plunger prevent the injection during the fluid drawing process. Claims 1, 2, 11 to 13, 16 and 21 lack novelty in view of this document. The presence of two pawls and two ratchets that are both designed to prevent plunger withdrawal after injection is considered to be an obvious variation of D2 and within the ability of the person skilled in the art. Claims 3, 4, 14 and 15 are considered to lack an inventive step in view of this document.

D3 is directed to a syringe with a double pawl mechanism mounted on a separate collar (figure 1). The pawls engage with serrations on the plunger (figure 3) to block movement of the plunger back from the injection stroke. Claims 1 to 4, 11 to 16 and 21 lack novelty and therefore an inventive step in view of this document.

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International Application No.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

In Document D4, the plunger has two sets of serrations (A, B) arranged in opposite directions to each other. A mechanism (M), prevents the plunger from moving in one of the directions. A different mechanism prevents serrations A from being used twice. It is considered that the matter of claims 1, 11 and 21 lack novelty and also an inventive step in view of this document.

Document D5 is directed to mechanisms preventing rearward movement of a plunger using ratchet on the plunger and detent (60) mounted to flexible insert (57). Insert also includes an alignment member (59) (see figure 2). Claims 1, 11 and 21 lack novelty in view of this embodiment. D5 includes a further embodiment (figure 11), wherein two ratchet portions are mounted to the interior of the housing and two detent portions are mounted on the plunger. It is submitted that the person skilled in the art would readily adapt this arrangement to the first embodiment of D5 and arrive at the disclosure of claims 2 to 4 and 12 to 16. Claims 1 to 4, 11 to 16 and 21 lack an inventive step in view of this document.

D6 provides a plunger with two sets of grooves (24, 26) and two pawls (34) facing in opposite directions. As was discussed with D2, claims 1, 2, 11 to 13, 16 and 21 lack novelty in view of D6. Claims 3, 4, 14 and 15 lack an inventive step as being an obvious variation of D6 in view of the common general knowledge of the art.

D7 is directed to a simple ratchet on the plunger and separate pawl mechanism to prevent reuse of a syringe. Claim 1, 11, and 21 lack novelty and also an inventive step in view of this document.